Complete Summary

GUIDELINE TITLE

Recommendations for preventing transmission of infections among chronic hemodialysis patients.

BIBLIOGRAPHIC SOURCE(S)

Recommendations for preventing transmission of infections among chronic hemodialysis patients. MMWR Recomm Rep 2001 Apr 27;50(RR-5):1-43. [54 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Bloodborne virus infections, such as:
 - Hepatitis B virus infection
 - Hepatitis C virus infection
 - Hepatitis delta virus infection
 - Human immunodeficiency virus infection
- Bacterial infections

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice Infectious Diseases Internal Medicine Nephrology Preventive Medicine

INTENDED USERS

Health Care Providers Hospitals Public Health Departments

GUIDELINE OBJECTIVE(S)

- To present recommendations for the prevention of bacterial infection and bloodborne virus infections in hemodialysis centers
- To provide guidelines for a comprehensive infection control program that includes: (a) infection control practices specifically designed for the hemodialysis setting, including routine serologic testing and immunization; (b) surveillance; and (c) training and education
- To provide a resource for health-care professionals, public health officials, and organizations involved in the care of patients receiving hemodialysis

TARGET POPULATION

Chronic hemodialysis patients

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Infection control practices for hemodialysis units:
 - a. Precautions for all patients (for example, hygiene, protective equipment, handling and delivery of medications)
 - b. Cleaning and disinfection
 - c. Additional precautions for patients at increased risk for transmitting pathogenic bacteria (for example, use of gowns by health care workers)
- 2. Routine serologic testing of patients for hepatitis B virus and hepatitis C virus infections (alanine aminotransferase, antibody to hepatitis B core antigen, antibody to hepatitis B surface antigen, antibody to hepatitis C virus, hepatitis B core antigen, hepatitis B surface antigen).
- Selective testing for hepatitis D virus (antibody to hepatitis D virus) and human immunodeficiency virus (HIV).
 [Note: Routine testing for hepatitis D virus and HIV are considered but not recommended. Also, routine testing of staff members for hepatitis C virus, hepatitis D virus, and HIV is considered but not recommended.]
- 4. Hepatitis B vaccination (RecombivaxHB™ and Engerix-B[R] vaccines) of patients and hemodialysis staff members.
- 5. Isolation of patients depending on serologic status.
- 6. Surveillance for infections and other adverse events (centralized record keeping to monitor and prevent complications).
- 7. Infection control training and education, as needed, for staff, patients, and family members of patients.

MAJOR OUTCOMES CONSIDERED

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Components of a Comprehensive Infection Control Program to Prevent Transmission of Infections Among Chronic Hemodialysis Patients

- 1. Infection control practices for hemodialysis units:
 - Infection control precautions specifically designed to prevent transmission of bloodborne viruses and pathogenic bacteria among patients
 - Routine serologic testing for hepatitis B virus and hepatitis C virus infections
 - Vaccination of susceptible patients against hepatitis B
 - Isolation of patients who test positive for hepatitis B surface antigen
- 2. Surveillance for infections and other adverse events
- 3. Infection control training and education.

Infection Control Practices for Hemodialysis Units

In each chronic hemodialysis unit, policies and practices should be reviewed and updated to ensure that infection control practices recommended for hemodialysis units are implemented and rigorously followed (see the section titled "Recommended Infection Control Practices for Hemodialysis Units at a Glance," below). Intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.

Recommended Infection Control Practices for Hemodialysis Units at a Glance

Infection Control Precautions for All Patients

- 1. Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station; remove gloves and wash hands between each patient or station.
- 2. Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient:
 - Nondisposable items that cannot be cleaned and disinfected (for example, adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use only on a single patient
 - Unused medications (including multiple dose vials containing diluents)
 or supplies (for example, syringes, alcohol swabs) taken to the
 patient's station should be used only for that patient and should not
 be returned to a common clean area or used on other patients
- 3. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away

- from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.
- 4. Do not use common medication carts to deliver medications to patients. Do not carry medication vials syringes, alcohol swabs, or supplies in pockets. If trays are used to deliver medications to individual patients, they must be cleaned between patients.
- 5. Clean areas should be clearly designated for the preparation, handling, and storage of medications and unused supplied and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to where used equipment or blood sample are handled.
- 6. Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines pressure monitors. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.
- 7. Clean and disinfect the dialysis station (for example, chairs, beds, tables, machines) between patients:
 - Give special attention to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated with patients blood
 - Discard all fluid and clean and disinfect all surfaces and containers associated with the prime waste (including buckets attached to the machines)
- 8. For dialyzers and blood tubing that will be reprocessed, cap dialyzer ports and clamp tubing. Place all used dialyzers and tubing in leakproof containers for transport from station to reprocessing or disposal area.

Schedule for Routine Testing for Hepatitis B Virus and Hepatitis C Virus Infections

| Patient Status | On Admission | Monthly | Semiannual | Annual |
|-------------------|--|---------|------------|--------|
| All patients | Hepatitis B surface antigen* | | | |
| | Antibody to hepatitis B core antigen* (total) | | | |
| | Antibody to hepatitis B surface antigen* | | | |
| | Antibody to hepatitis C | | | |

| | virus* Alanine aminotransfer ase | | | | |
|---|---|--|-------------------------------------|--|--|
| Hepatitis B virus- susceptible, including nonrespond ers to vaccine | | Hepatitis B surface antigen | | | |
| Antibody to hepatitis B surface antigen positive (greater than or equal to 10 mIU/mL) | | | | Antibody to hepatitis B surface antigen | |
| Antibody to hepatitis B core antigen negative | | | | | |
| Antibody to hepatitis B surface antigen Antibody to hepatitis B | | No additional hepatitis B virus testing needed | | | |
| core antigen positive | | | | | |
| Antibody to hepatitis C virus negative | | Alanine aminotransfer ase | Antibody to hepatitis C virus | | |
| *Results of hepatitis B virus testing should be known before the patient begins dialysis. | | | | | |

Hepatitis B Vaccination

- 1. Vaccinate all susceptible patients against hepatitis B.
- 2. Test for antibody to hepatitis B surface antigen 1-2 months after last dose:
 - If antibody to hepatitis B surface antigen is less than 10 mIU/milliliter, consider patient susceptible, revaccinate with an additional three doses, and retest for antibody to hepatitis B surface antigen
 - If antibody to hepatitis B surface antigen is equal to or greater than 10 mIU/milliliter, consider patient immune, and retest annually:
 - Give booster dose of vaccine if antibody to hepatitis B surface antigen declines to less than 10 mlU/milliliter and continue to retest annually

Management of Hepatitis B Surface Antigen-Positive Patients

- 1. Follow infection control practices for hemodialysis units for all patients.
- 2. Dialyze hepatitis B surface antigen-positive patients in a separate room using separate machines, equipment, instruments, and supplies.
- 3. Staff members caring for hepatitis B surface antigen-positive patients should not care for hepatitis B virus-susceptible patients at the same time (for example, during the same shift or during patient changeover).

Infection Control Precautions for All Patients

During the process of hemodialysis, exposure to blood and potentially contaminated items can be routinely anticipated; thus, gloves are required whenever caring for a patient or touching the patient's equipment. To facilitate glove use, a supply of clean nonsterile gloves and a glove discard container should be placed near each dialysis station. Hands always should be washed after gloves are removed and between patient contacts, as well as after touching blood, body fluids, secretions, excretions, and contaminated items. A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. If hands are not visibly soiled, use of a waterless antiseptic hand rub can be substituted for hand washing.

Any item taken to a patient's dialysis station could become contaminated with blood and other body fluids and serve as a vehicle of transmission to other patients either directly or by contamination of the hands of personnel. Therefore, items taken to a patient's dialysis station, including those placed on top of dialysis machines, should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being returned to a common clean area or used for other patients. Unused medications or supplies (e.g., syringes, alcohol swabs) taken to the patient's station should not be returned to a common clean area or used on other patients.

Additional measures to prevent contamination of clean or sterile items include (a) preparing medications in a room or area separated from the patient treatment area and designated only for medications; (b) not handling or storing contaminated (i.e., used) supplies, equipment, blood samples, or biohazard containers in areas where medications and clean (i.e., unused) equipment and supplies are handled; and (c) delivering medications separately to each patient. Common carts should not be used within the patient treatment area to prepare or distribute medications. If trays are used to distribute medications, clean them before using for a different patient.

Intravenous medication vials labeled for single use, including erythropoetin, should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial.

If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.

Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Such protective clothing or gear should be changed if it becomes soiled with blood, body fluids, secretions, or excretions. Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. However, patients can be served meals or eat food brought from home at their dialysis station. The glasses, dishes, and other utensils should be cleaned in the usual manner; no special care of these items is needed.

Cleaning and Disinfection. Establish written protocols for cleaning and disinfecting surfaces and equipment in the dialysis unit, including careful mechanical cleaning before any disinfection process (see the table titled "Disinfection Procedures Recommended for Commonly Used Items or Surfaces in Hemodialysis Units," below). If the manufacturer has provided instructions on sterilization or disinfection of the item, these instructions should be followed. For each chemical sterilant and disinfectant, follow the manufacturer's instructions regarding use, including appropriate dilution and contact time.

Disinfection Procedures Recommended for Commonly Used I tems or Surfaces in Hemodialysis Units

| I tem or Surface | Low-Level Disinfectio n* | Intermediate- Level Disinfection* |
|--|--------------------------------|---|
| Gross blood spills or items contaminated with visible blood | | Х |
| Hemodialyzer port caps | | X |
| Interior pathways of dialysis machine | | X |
| Water treatment and distribution system | X | X** |
| Scissors, hemostats, clamps, blood pressure cuffs, stethoscopes | X | X*** |
| Environmental surfaces, including exterior surfaces of hemodialysis machines | X | |

*Careful mechanical cleaning to remove debris should always be done before disinfection.

After each patient treatment, clean environmental surfaces at the dialysis station, including the dialysis bed or chair, countertops, and external surfaces of the dialysis machine, including containers associated with the prime waste. Use any soap, detergent, or detergent germicide. Between uses of medical equipment (e.g., scissors, hemostats, clamps, stethoscopes, blood pressure cuffs), clean and apply a hospital disinfectant (i.e., low-level disinfection); if the item is visibly contaminated with blood, use a tuberculocidal disinfectant (i.e., intermediate-level disinfection).

For a blood spill, immediately clean the area with a cloth soaked with a tuberculocidal disinfectant or a 1:100 dilution of household bleach (300 to 600 mg/L free chlorine) (i.e., intermediate-level disinfection). The staff member doing the cleaning should wear gloves, and the cloth should be placed in a bucket or other leakproof container. After all visible blood is cleaned, use a new cloth or towel to apply disinfectant a second time.

Published methods should be used to clean and disinfect the water treatment and distribution system and the internal circuits of the dialysis machine, as well as to reprocess dialyzers for reuse (see "Suggested Readings" in the original guideline document). These methods are designed to control bacterial contamination, but will also eliminate bloodborne viruses. For single-pass machines, perform rinsing and disinfection procedures at the beginning or end of the day. For batch recirculating machines, drain, rinse, and disinfect after each use. Follow the same methods for cleaning and disinfection if a blood leak has occurred, regardless of the type of dialysis machine used. Routine bacteriologic assays of water and dialysis fluids should be performed according to the recommendations of the Association for the Advancement of Medical Instrumentation (see "Suggested Readings" in the original guideline document).

Venous pressure transducer protectors should be used to cover pressure monitors and should be changed between patients, not reused. If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300 to 600 mg/L free chlorine) or a commercially available, U. S. Environmental Protection Agency-registered tuberculocidal germicide before reuse. Frequent blood line pressure alarms or frequent adjusting of blood drip chamber levels can be an indicator of this problem. Taken separately, these incidents could be characterized as isolated malfunctions. However, the potential public health significance of the total number of incidents

^{**}Water treatment and distribution systems of dialysis fluid concentrates require more extensive disinfection if significant biofilm is present within the system.

^{***}If item is visibly contaminated with blood, use a tuberculocidal disinfectant

nationwide make it imperative that all incidents of equipment contamination be reported immediately to the U. S. Food and Drug Administration (800-FDA-1088 [U.S. only]).

Housekeeping staff members in the dialysis facility should promptly remove soil and potentially infectious waste and maintain an environment that enhances patient care. All disposable items should be placed in bags thick enough to prevent leakage. Wastes generated by the hemodialysis facility might be contaminated with blood and should be considered infectious and handled accordingly. These solid medical wastes should be disposed of properly in an incinerator or sanitary landfill, according to local and state regulations governing medical waste disposal.

Hemodialysis in Acute-Care Settings. For patients with acute renal failure who receive hemodialysis in acute-care settings, Standard Precautions as applied in all health-care settings are sufficient to prevent transmission of bloodborne viruses. However, when chronic hemodialysis patients receive maintenance hemodialysis while hospitalized, infection control precautions specifically designed for chronic hemodialysis units (see the section titled "Recommended Practices at a Glance") should be applied to these patients. If both acute and chronic renal failure patients receive hemodialysis in the same unit, these infection control precautions should be applied to all patients.

Regardless of where in the acute-care setting chronic hemodialysis patients receive dialysis, the hepatitis B surface antigen status of all such patients should be ascertained at the time of admission to the hospital, by either a written report from the referring center (including the most recent date testing was performed) or by a serologic test. The hepatitis B virus serologic status should be prominently placed in patients' hospital records, and all health-care personnel assigned to these patients, as well as the infection control practitioner, should be aware of the patients' serologic status. While hospitalized, hepatitis B surface antigen-positive chronic hemodialysis patients should undergo dialysis in a separate room and use separate machines, equipment, instruments, supplies, and medications designated only for hepatitis B surface antigen-positive patients (see the section titled "Prevention and Management of Hepatitis B Virus Infection"). While hepatitis B surface antigen-positive patients are receiving dialysis, staff members who are caring for them should not care for susceptible patients.

Routine Serologic Testing

Chronic Hemodialysis Patients. Routinely test all chronic hemodialysis patients for hepatitis B virus and hepatitis C virus infection (see the section titled "Recommended Practices at a Glance"), promptly review results, and ensure that patients are managed appropriately based on their testing results (see later recommendations for each virus). Communicate test results (positive and negative) to other units or hospitals when patients are transferred for care. Routine testing for hepatitis D virus or human immunodeficiency virus (HIV) infection for purposes of infection control is not recommended.

The hepatitis B virus serologic status (i.e., hepatitis B surface antigen, total antibody to hepatitis B core antigen, and antibody to hepatitis B surface antigen) of all patients should be known before admission to the hemodialysis unit. For

patients transferred from another unit, test results should be obtained before the patients' transfer. If a patient's hepatitis B virus serologic status is not known at the time of admission, testing should be completed within 7 days. The hemodialysis unit should ensure that the laboratory performing the testing for antibody to hepatitis B surface antigen can define a 10 mIU/mL concentration to determine protective levels of antibody.

Routine hepatitis C virus testing should include use of both an enzyme immunoassay to test for antibody to hepatitis C virus and supplemental or confirmatory testing with an additional, more specific assay (see the related figure in the original guideline document). Use of reverse transcriptase polymerase chain reaction for hepatitis C virus RNA as the primary test for routine screening is not recommended because few hepatitis C virus infections will be identified in antibody to hepatitis C virus negative patients. However, if alanine aminotransferase levels are persistently abnormal in patients who are antibody to hepatitis C virus negative in the absence of another etiology, testing for hepatitis C virus RNA should be considered (for proper specimen collection and handling, see the section titled "Hepatitis C Virus Infection, Screening and Diagnostic Tests").

Hemodialysis Staff Members. Previously, testing for hepatitis B virus infection was recommended for all staff members at the time of employment and for susceptible staff members at routine intervals thereafter; however, such testing is no longer considered necessary. The risk for hepatitis B virus infection among hemodialysis staff members is no greater than that for other health-care workers. Thus, routine testing of staff members is not recommended except when required to document response to hepatitis B vaccination (see the section titled "Postvaccination Testing and Revaccination of Nonresponders"). Routine testing of staff members for hepatitis C virus, hepatitis D virus, or HIV infection is not recommended.

Hepatitis B Vaccination

Vaccine Schedule and Dose. Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients and for all staff members (see Table 3 in the original guideline document). Vaccination is recommended for pre-end-stage renal disease patients before they become dialysis dependent and for peritoneal and home dialysis patients because they might require in-center hemodialysis. Hepatitis B vaccine should be administered by the intramuscular route and only in the deltoid muscle for adults and children. Intradermal or subcutaneous administration of hepatitis B vaccine is not recommended.

If an adult patient begins the vaccine series with a standard dose before beginning hemodialysis treatment, then moves to hemodialysis treatment before completing the series, complete the series using the higher dose recommended for hemodialysis patients (see Table 3 in the original guideline document). No specific recommendations have been made for higher doses for pediatric hemodialysis patients. If a lower than recommended vaccine dose is administered to either adults or children, the dose should be repeated.

If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. For the three-dose primary vaccine series, the second and third doses should be separated by an interval of at least 2 months; if only the third dose is delayed, that dose should be administered when convenient. When hepatitis B vaccine has been administered at the same time as other vaccines, no interference with the antibody response of the other vaccines has been demonstrated.

Postvaccination Testing and Revaccination of Nonresponders. Test all vaccinees for antibody to hepatitis B surface antigen 1--2 months after the last primary vaccine dose, to determine their response to the vaccine (adequate response is defined as greater than or equal to 10 mIU/mL). Patients and staff members who do not respond to the primary vaccine series should be revaccinated with three additional doses and retested for response. No additional doses of vaccine are warranted for those who do not respond to the second series.

Evaluate staff members who do not respond to revaccination to determine if they are hepatitis B surface antigen positive. Persons who are hepatitis B surface antigen positive should be counseled accordingly (e.g., need for medical evaluation, vaccination of sexual and household contacts). Primary nonresponders to vaccination who are hepatitis B surface antigen negative should be considered susceptible to hepatitis B virus infection and counseled regarding precautions to prevent hepatitis B virus infection and the need to obtain postexposure prophylaxis with hepatitis B immune globulin for any known or probable percutaneous or mucosal exposure to hepatitis B surface antigen-positive blood.

Follow-Up of Vaccine Responders. Retest patients who respond to the vaccine annually for antibody to hepatitis B surface antigen. If antibody to hepatitis B surface antigen declines to less than 10 mIU/mL, administer a booster dose of hepatitis B vaccine and continue to retest annually. Retesting immediately after the booster dose is not necessary. For staff members who respond to the vaccine, booster doses of vaccine are not necessary, and periodic serologic testing to monitor antibody concentrations is not recommended.

Patients with a History of Vaccination. Routine childhood vaccination against hepatitis B has been recommended since 1991 and routine adolescent vaccination since 1995. Thus, many persons who develop end-stage renal failure will have a history of vaccination against hepatitis B. These persons should have responded to the vaccine when their immune status was normal, but if their antibody to hepatitis B surface antigen levels are less than 10 mIU/mL when they begin dialysis, they should be revaccinated with a complete primary series.

Prevention and Management of Hepatitis B Virus Infection

Preventing hepatitis B virus transmission among chronic hemodialysis patients requires a) infection control precautions recommended for all hemodialysis patients; b) routine serologic testing for markers of hepatitis B virus infection and prompt review of results; c) isolation of hepatitis B surface antigen-positive patients with dedicated room, machine, other equipment, supplies, and staff members; and d) vaccination. Additional infection control practices are needed because of the potential for environmentally mediated transmission of hepatitis B virus, rather than internal contamination of dialysis machines. The need for routine follow-up testing, vaccination, or isolation is based on patients' serologic

status (see Table 1 in the original guideline document and "Recommended Practices at a Glance").

Hepatitis B Virus-Susceptible Patients. Vaccinate all susceptible patients (see the section titled "Hepatitis B Vaccination"). Test susceptible patients monthly for hepatitis B surface antigen, including those who a) have not yet received hepatitis B vaccine, b) are in the process of being vaccinated, or c) have not adequately responded to vaccination. Although the incidence of hepatitis B virus infection is low among chronic hemodialysis patients, preventing transmission depends on timely detection of patients converting from hepatitis B surface antigen negative to hepatitis B surface antigen positive and rapid implementation of isolation procedures before cross-contamination can occur.

Hepatitis B Surface Antigen Seroconversions. Report hepatitis B surface antigen-positive seroconversions to the local health department as required by law or regulation. When a seroconversion occurs, review all patients' routine laboratory test results to identify additional cases. Perform additional testing as indicated later in this section. Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit, including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures.

In patients newly infected with hepatitis B virus, hepatitis B surface antigen often is the only serologic marker initially detected; repeat hepatitis B surface antigen testing and test for antibody to hepatitis B core antigen (including IgM antibody to hepatitis B core antigen) 1 to 2 months later. Six months later, repeat hepatitis B surface antigen testing and test for antibody to hepatitis B surface antigen to determine clinical outcome and need for counseling, medical evaluation, and vaccination of contacts. Patients who become hepatitis B surface antigen negative are no longer infectious and can be removed from isolation.

Hepatitis B Virus-Infected Patients. To isolate hepatitis B surface antigen-positive patients, designate a separate room for their treatment and dedicate machines, equipment, instruments, supplies, and medications that will not be used by hepatitis B virus-susceptible patients. Most importantly, staff members who are caring for hepatitis B surface antigen-positive patients should not care for susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.

Newly opened units should have isolation rooms for the dialysis of hepatitis B surface antigen-positive patients. For existing units in which a separate room is not possible, hepatitis B surface antigen-positive patients should be separated from hepatitis B virus-susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on dedicated machines. If a machine that has been used on an hepatitis B surface antigen-positive patient is needed for an hepatitis B virus-susceptible patient, internal pathways of the machine can be disinfected using conventional protocols and external surfaces cleaned using soap and water or a detergent germicide.

Dialyzers should not be reused on hepatitis B surface antigen-positive patients. Because hepatitis B virus is efficiently transmitted through occupational exposure

to blood, reprocessing dialyzers from hepatitis B surface antigen-positive patients might place hepatitis B virus-susceptible staff members at increased risk for infection.

Chronically infected patients (i.e., those who are hepatitis B surface antigen-positive, total antibody to hepatitis B core antigen positive, and IgM antibody to hepatitis B core antigen negative) are infectious to others and are at risk for chronic liver disease. They should be counseled regarding preventing transmission to others, their household and sexual partners should receive hepatitis B vaccine, and they should be evaluated (by consultation or referral, if appropriate) for the presence or development of chronic liver disease according to current medical practice guidelines. Persons with chronic liver disease should be vaccinated against hepatitis A, if susceptible.

Chronically infected patients do not require any routine follow-up testing for purposes of infection control. However, annual testing for hepatitis B surface antigen is reasonable to detect the small percentage of hepatitis B virus-infected patients who might lose their hepatitis B surface antigen.

Hepatitis B Virus-Immune Patients. Annual antibody to hepatitis B surface antigen testing of patients who are positive for antibody to hepatitis B surface antigen (greater than or equal to 10 mIU/mL) and negative for antibody to hepatitis B core antigen determines the need for booster doses of vaccine to ensure that protective levels of antibody are maintained. No routine follow-up testing is necessary for patients who are positive for both antibody to hepatitis B surface antigen and antibody to hepatitis B core antigen.

Hepatitis B virus-immune patients can undergo dialysis in the same area as hepatitis B surface antigen-positive patients, or they can serve as a geographic buffer between hepatitis B surface antigen-positive and hepatitis B virus-susceptible patients. Staff members can be assigned to care for both infected and immune patients on the same shift.

Isolated Antibody to Hepatitis B core antigen--Positive Patients. Patients who test positive for isolated antibody to hepatitis B core antigen (i.e., those who are antibody to hepatitis B core antigen positive, hepatitis B surface antigen negative, and antibody to hepatitis B surface antigen negative) should be retested on a separate serum sample for total antibody to hepatitis B core antigen, and if positive, for IgM antibody to hepatitis B core antigen. The following guidelines should be used for interpretation and follow-up:

- If total antibody to hepatitis B core antigen is negative, consider patient susceptible, and follow recommendations for vaccination.
- If total antibody to hepatitis B core antigen is positive and IgM antibody to hepatitis B core antigen is negative, follow recommendations for vaccination:
 - If antibody to hepatitis B surface antigen is less than 10 mIU/mL even after revaccination, test for hepatitis B virus DNA
 - If hepatitis B virus DNA is negative, consider patient susceptible (i.e., the antibody to hepatitis B core antigen result is a false positive), and test monthly for hepatitis B surface antigen

- If hepatitis B virus DNA is positive, consider patient as having past infection or "low-level" chronic infection (i.e., the antibody to hepatitis B core antigen result is a true positive); no further testing is necessary
- Isolation is not necessary because hepatitis B surface antigen is not detectable
- If both total and IgM antibody to hepatitis B core antigen are positive, consider patient recently infected and test for antibody to hepatitis B surface antigen in 4--6 months; no further routine testing is necessary:
 - Isolation is not necessary because hepatitis B surface antigen is not detectable

Prevention and Management of Hepatitis C Virus Infection

Hepatitis C virus transmission within the dialysis environment can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients (see the section titled "Recommended Practices at a Glance"). Although isolation of hepatitis C virus-infected patients is not recommended, routine testing for alanine aminotransferase and antibody to hepatitis C virus is important for monitoring transmission within centers and ensuring that appropriate precautions are being properly and consistently used.

Hepatitis C Virus-Negative Patients. Monthly alanine aminotransferase testing will facilitate timely detection of new infections and provide a pattern from which to determine when exposure or infection might have occurred. In the absence of unexplained alanine aminotransferase elevations, testing for antibody to hepatitis C virus every 6 months should be sufficient to monitor the occurrence of new hepatitis C virus infections. If unexplained alanine aminotransferase elevations are observed in patients who are antibody to hepatitis C virus negative, repeat antibody to hepatitis C virus testing is warranted. If unexplained alanine aminotransferase elevations persist in patients who repeatedly test antibody to hepatitis C virus negative, testing for hepatitis C virus RNA should be considered.

Antibody to Hepatitis C Virus Seroconversions. Report antibody to hepatitis C virus-positive seroconversions to the local health department as required by law or regulation. When a seroconversion occurs, review all other patients' routine laboratory test results to identify additional cases. Perform additional testing as indicated later in this section. Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit, including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures.

If <u>more than</u> one patient seroconverts from antibody to hepatitis C virus negative to positive during a 6-month period, more frequent (e.g., every 1 to 3 months) antibody to hepatitis C virus testing of hepatitis C virus-negative patients could be warranted for a limited time (e.g., 3 to 6 months) to detect additional infections. If no additional newly infected patients are identified, resume semiannual testing. If ongoing hepatitis C virus transmission among patients is identified, implement control measures based on results of investigation of potential sources for transmission and monitor their effectiveness (e.g., perform more frequent antibody to hepatitis C virus testing of hepatitis C virus-negative patients for 6 to 12 months before resuming semiannual testing).

Hepatitis C Virus-Positive Patients. Patients who are antibody to hepatitis C virus positive (or hepatitis C virus RNA positive) do not have to be isolated from other patients or dialyzed separately on dedicated machines. Furthermore, they can participate in dialyzer reuse programs. Unlike hepatitis B virus, hepatitis C virus is not transmitted efficiently through occupational exposures. Thus, reprocessing dialyzers from hepatitis C virus-positive patients should not place staff members at increased risk for infection.

Hepatitis C virus-positive persons should be evaluated (by consultation or referral, if appropriate) for the presence or development of chronic liver disease according to current medical practice guidelines. They also should receive information concerning how they can prevent further harm to their liver and prevent transmitting hepatitis C virus to others. Persons with chronic liver disease should be vaccinated against hepatitis A, if susceptible.

Prevention and Management of Hepatitis D Virus Infection

Because of the low prevalence of hepatitis D virus infection in the United States, routine testing of hemodialysis patients is not necessary or recommended. However, if a patient is known to be infected with hepatitis D virus, or if evidence exists of transmission of hepatitis D virus in a dialysis center, screening for delta antibody is warranted. Because hepatitis D virus depends on an hepatitis B virus-infected host for replication, prevention of hepatitis B virus infection will prevent hepatitis D virus infection in a person susceptible to hepatitis B virus. Patients who are known to be infected with hepatitis D virus should be isolated from all other dialysis patients, especially those who are hepatitis B surface antigen-positive.

Prevention and Management of HIV Infection

Routine testing of hemodialysis patients for HIV infection for infection control purposes is not necessary or recommended. However, patients with risk factors for HIV infection should be tested so that, if infected, they can receive proper medical care and counseling regarding preventing transmission of the virus.

Infection control precautions recommended for all hemodialysis patients (see the section titled "Recommended Practices at a Glance") are sufficient to prevent HIV transmission between patients. HIV-infected patients do not have to be isolated from other patients or dialyzed separately on dedicated machines. In addition, they can participate in dialyzer reuse programs. Because HIV is not transmitted efficiently through occupational exposures, reprocessing dialyzers from HIV-positive patients should not place staff members at increased risk for infection.

Prevention and Management of Bacterial Infections

Follow published guidelines for judicious use of antimicrobials, particularly vancomycin, to reduce selection for antimicrobial-resistant pathogens. Infection control precautions recommended for all hemodialysis patients (see the section titled "Recommended Practices at a Glance") are adequate to prevent transmission for most patients infected or colonized with pathogenic bacteria, including antimicrobial-resistant strains. However, additional infection control precautions should be considered for treatment of patients who might be at increased risk for transmitting pathogenic bacteria. Such patients include those

with either (a) an infected skin wound with drainage that is not contained by dressings (the drainage does not have to be culture positive for vancomycin-resistant enterococci, Methicillin-resistant Staphylococcus aureus, or any specific pathogen) or (b) fecal incontinence or diarrhea uncontrolled with personal hygiene measures. For these patients, consider using the following additional precautions: (a) staff members treating the patient should wear a separate gown over their usual clothing and remove the gown when finished caring for the patient and (b) dialyze the patient at a station with as few adjacent stations as possible (e.g., at the end or corner of the unit).

Surveillance For Infections And Other Adverse Events

Develop and maintain a separate centralized record-keeping system (e.g., log book or electronic file) to record the results of patients' vaccination status, serologic testing results for viral hepatitis (including alanine aminotransferase), episodes of bacteremia or loss of the vascular access caused by infection (including date of onset, site of infection, genus and species of the infecting organism, and selected antimicrobial susceptibility results),* and adverse events (e.g., blood leaks and spills, dialysis machine malfunctions). Designate a staff person to promptly review the results of routine testing each time such testing is performed and periodically review recorded episodes of bacteremia or vascular access infections. Specify a procedure for actions required when changes occur in test results or in the frequency of episodes of bacteremias or vascular access loss because of infection. Maintain records for each patient that include the location of the dialysis station and machine number used for each dialysis session and the names of staff members who connect and disconnect the patient to and from a machine.

* Hemodialysis units interested in participating in a formal surveillance system for bacterial infections should consult the Centers for Disease Control and Prevention's "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers." More information is available at the <u>Centers for Disease Control and Prevention Web site.</u>

Infection Control Training And Education

Training and education is recommended for both staff members and patients (or their family care givers). Training should be appropriate to the cognitive level of the staff member, patient, or family member, and rationales should be provided for appropriate infection control behaviors and techniques to increase compliance. Regulations and recommendations regarding infection control training for health-care workers in general, and dialysis personnel in particular, have been previously published. The following recommendations are intended to highlight and augment the earlier recommendations.

- Training and education for all employees at risk for occupational exposure to blood should be provided at least annually, given to new employees before they begin working in the unit, and documented. At a minimum, they should include information on the following topics:
 - proper hand hygiene technique
 - proper use of protective equipment

- modes of transmission for bloodborne viruses, pathogenic bacteria, and other microorganisms as appropriate
- infection control practices recommended for hemodialysis units and how they differ from Standard Precautions recommended for other health-care settings
- proper handling and delivery of patient medications
- rationale for segregating hepatitis B surface antigen-positive patients with a separate room, machine, instruments, supplies, medications, and staff members
- proper infection control techniques for initiation, care, and maintenance of access sites
- housekeeping to minimize transmission of microorganisms, including proper methods to clean and disinfect equipment and environmental surfaces
- centralized record keeping to monitor and prevent complications, including routine serologic testing results for hepatitis B virus and hepatitis C virus, hepatitis B vaccine status, episodes of bacteremia and loss of access caused by infection, and other adverse events. Records of surveillance for water and dialysate quality should also be maintained
- Training and education of patients (or family members for patients unable to be responsible for their own care) regarding infection control practices should be given on admission to dialysis and at least annually thereafter and should address the following topics:
 - personal hygiene and hand washing technique
 - patient responsibility for proper care of the access and recognition of signs of infection, which should be reviewed each time the patient has a change in access type; and recommended vaccinations

CLINICAL ALGORITHM(S)

An algorithm is provided for hepatitis C virus infection testing among persons who are asymptomatic.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Implementation of the recommended comprehensive infection control program in hemodialysis centers will reduce opportunities for patient-to-patient transmission of infectious agents, directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel, and thereby decrease rates of bacterial infection and bloodborne virus infections among chronic hemodialysis patients.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These recommendations do not address sources of bacterial and chemical contaminants in dialysis systems, water treatment or distribution, specific procedures for reprocessing dialyzers, clinical practice methods to prevent bacterial infections (for example, techniques for skin preparation and access), or comprehensive strategies for preventing infections among health-care workers.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Recommendations for preventing transmission of infections among chronic hemodialysis patients. MMWR Recomm Rep 2001 Apr 27;50(RR-5):1-43. [54 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

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Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Centers</u> <u>for Disease Control and Prevention (CDC) Web site</u>.

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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